## CARES Act Drug Amount Information Reporting: CSV Template Instructions for a Drug Product Which Is Not in Finished Package Form

PURPOSE

Generalized instructions for populating the provided template for uploading drug or biological product amount information for a drug product which is not in finished package form via a CSV file. Please refer to the Technical Conformance Guide – Guidance for Industry on the FDA CARES Act Drug Shortage Mitigation Efforts webpage for definitions of the data elements.

Download the CARES Template for CSV Data Upload from the NextGen Portal—CARES Act Drug Amount Information Reporting or from the FDA Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Drug Shortage Mitigation Efforts webpage.

#### **REVIEW THE FOLLOWING INFORMATION BEFORE COMPLETING THE CSV FILE**

FDA is offering the option to upload a CSV file containing the required CARES Act Drug Amount Information to reduce the burden of submitting large quantities of data to the Agency. For smaller submissions that would be easier to enter manually, it is recommended to utilize **the manual entry method in** the NextGen Reporting tool. For larger submissions, it is recommended to utilize the submission of a CSV file.

For the most efficient processing, files should contain less than 200k rows in total. If a submission contains more than 200k rows, it should be split into separate files which contain less than 200k rows each, and each file should be submitted separately. When splitting files, ensure that the split does not occur between months for a single DUNS – NDC – Business Operation combination; the split should occur after an "Annual Total" row.

It is highly recommended to populate the CSV template by opening the file in Notepad to retain formatting and leading zeroes on reported DUNS and NDCs. However, if you plan to use Excel, please make edits and save the file as .xlsx instead of .csv if making periodic updates. After making your final edits to the document, follow the steps listed below in Section 2.0 to save the document as a .csv extension type so it can be properly uploaded into the NextGen Portal—CARES Act Drug Amount Information Reporting.

Upon making the final edit and before uploading, please make sure you save the file as a .csv extension type file to ensure the file is successfully uploaded into the NextGen Portal—CARES Act Drug Amount Information Reporting.

For the data that requires you to use the listed permissible values, copy and paste the value to avoid typos or misspellings.

The steps below outline how to enter one drug product which is not in finished package form in the template. This process should be repeated for all listed drugs.

SECTION 1.0	Listed drug product which is not in finished package form			
COLUMN	INSTRUCTIONS	VALIDATION		
Column A Row 2	Starting in Column A, Row 2 (Establishment DUNS). Enter an Establishment DUNS number.	Exclude dashes and enter the digits only. Include any leading zeroes. Must be a 9-digit number.		
Column B Row 2	Continuing in Column B, Row 2 (Business Operation). Enter a Business Operation for the Establishment.	There is a fixed list of permissible values. Use only the values below: Manufacture Repack Relabel Transfill Positron Emission Tomography Drug Production Copy and paste values from this list to avoid misspellings or typos.		
Column C Row 2	Continuing in Column C, Row 2 (NDC). Enter the NDC of a listed drug.	Must include hyphens and digits. Include any leading zeroes. NDCs must be appropriately formatted in one of the following configurations: 4-4-2 (e.g., 1234-5678-90), 5-4-1 (e.g., 12345-6789-1), or 5-3-2 (e.g., 12345-678-90).		
Column D Row 2	Continuing in Column D, Row 2 (Source NDC). Enter a Source NDC <b>only</b> if the selected Business Operation in Column B, Row 2 is " <b>Relabel</b> " or " <b>Repack</b> ".	Must include hyphens and digits. Include any leading zeroes. NDCs must be appropriately formatted in one of the following configurations: 4-4-2 (e.g., 1234-5678-90), 5-4-1 (e.g., 12345-6789-1), 5-3-2 (e.g., 12345-678-90).		
Column E Row 2	Continuing in Column D, Row 2 (Amount Per). The value " <b>January</b> " should appear in the cell.	The month must be spelled out in English (as in the template) and not abbreviated. The months must be listed in calendar order (January through December).		
Column F Row 2	Continuing in Column E, Row 2 (Quantity Manufactured). Enter the Quantity Manufactured in <b>January</b> .	Can be a whole number or a decimal. If no listed drug was manufactured in the U.S. in January, enter 0.		
Column G Row 2	Continuing in Column F, Row 2 (Quantity Distributed (Non-US)). Enter the Quantity Distributed (Non-US) in <b>January</b> .	Can be a whole number or a decimal. To be entered only if seeking to use CARES Act Drug Amount Information reporting to satisfy distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a). If seeking to satisfy requirements under 21 CFR 314.81(b)(2)(ii)(a) and no listed drug was distributed in the foreign market in a month, enter 0. For details, please review QUESTIONS AND ANSWERS (B) in the guidance for industry.		

Column H Row 2	Continuing in Column G, Row 2 (Dosage Form Units). Enter the Dosage Form Units.	Enter a valid dosage form unit of measure. See <b>Appendix: Figure 2</b> for permissible values. *Copy and paste the value from this list to avoid misspellings or typos.	
Column I Row 2	Continuing in Column L, Row 2 (Intended to Fulfill 21 CFR 314.81). Enter " <b>Yes</b> " if the CARES Act Drug Amount Information submission is intended to satisfy the distribution data requirements under 21 CFR 314.81 (b) (2) (ii) (a). Monthly Values only (Refer to Column L Row 14 instructions for Annual	Permissible values: Yes No Blank	
	Total) Copy the information from Row 2, Columns A, B, C, D, and G down to		
Columns	Rows 3–14.		
A, B, C, D, G Rows 3-14	Column A: Establishment DUNS Column B: Business Operation Column C: NDC Column D: Source NDC (if applicable) Column G: Dosage Form Units	Columns A, B, C, D, and G should contain the same data in rows 2–14.	
	Column E, Rows 3-13 The remaining months of the year should be listed in these cells (February – December): Column E, Row 3 should be " <b>February</b> ," Column E, Row 4 should be " <b>March</b> ," etc.		
Column E Row 14	Column E, Row 14 The value " <b>Annual Total</b> " should be listed in the cell.	Rows 2–14 comprise a record for one listed drug.	
		Permissible values: Yes No	
Column I Row 14	Column I, Row 14 (Annual Total)	Enter " <b>Yes</b> " if the CARES Act Drug Amount Information submission for the listed drug is intended to satisfy the distribution data requirements under 21 CFR 314.81(b)(2)(ii)(a). The value listed in this field must match the values listed in the monthly fields for the same drug product (if entered).	

The steps below outline how to enter amount information for the remaining months and the total annual amount.

Column F Row 3-13 – Monthly Amounts	Column F (Quantity Manufactured), Rows 3–13 (February– December). Enter the Quantity Manufactured of the listed drug <b>for the remaining</b> <b>months</b> .	Can be a whole number or a decimal. If no listed drug was manufactured in the U.S. in a particular month, enter 0.	
Column F Row 14 – Annual Amount	Column F (Quantity Manufactured), Row 14 (Annual Total). Enter the Quantity Manufactured of the listed drug <b>during the</b> <b>reporting year</b> . This should be a total of values entered for January – December.	Can be a whole number or a decimal.	
Column G Row 3-13 – Monthly Amount	Column G (Quantity Distributed (Non-US)), Rows 3–13 (February– December). Enter the Quantity Distributed (Non-US) of the listed drug <b>for the</b> <b>remaining months</b> .	Can be a whole number or a decimal. To be entered only if seeking to use CARES Act Drug Amount Information reporting to satisfy distribution data requirements under 21 CFR 314.81 (b) (2) (ii) (a). If seeking to satisfy requirements under 21 CFR 314.81 (b) (2) (ii) (a) or 21 CFR 600.81 (a) and no listed drug was distributed in the foreign market in a month, enter 0. For details, please review QUESTIONS AND ANSWERS (B) in the guidance for industry.	
Column G Row 14 – Annual Amount	Column G (Quantity Distributed (Non-US)), Row 14 (Annual Total). Enter the Quantity Distributed (Non-US), of the listed drug <b>during the</b> <b>reporting year</b> . This should be a total of values entered for January– December.	Can be a whole number or a decimal. To be entered only if seeking to use CARES Act Drug Amount Information reporting to satisfy distribution data requirements under 21 CFR 314.81 (b) (2) (ii) (a). For details, please review QUESTIONS AND ANSWERS (B) in the guidance for industry.	

Section 2.0	aving CSV Template	

STEP NUMBER / ID	INSTRUCTIONS	ILLUSTRATION OF STEP
1	Verify that the sheet / tab containing the data is the active sheet / tab.	
2	Select <b>File</b> and <b>Save As</b>	Good afternoon   Home   New   Open   Info   Save   Save   Save Ac   Save as Adobe   Por   Print   Recent   Pinned   Share   Name

3	Locate the desired location to save the file in and select to save it as the <b>CSV (Comma delimited)</b> (*.csv) file extension type. Please note: There are several (*.csv) file extension type options. The option labeled <b>CSV (Comma delimited)</b> (*.csv) should be selected.	Evel Workbook (*.kto)         Evel Workbook (*.kto)         Evel Workbook (*.kto)         CSU UF-8 (Comme delimited) (*.a)         CSU UF-8 (Comme delimited) (*.a)         CSU UF-8 (Comme delimited) (*.a)         Wee Page (*.attr:*.attrin)         Evel Workbook (*.attrin)         Evel Workbook (*.attrin)
4	Save the file. NOTE: Do not reopen the saved .csv file after saving and prior to uploading. If the saved CSV file needs to be updated before uploading, be sure to save it with the .csv extension.	
5	Upload the data from the file into the system by following the instructions in the system. The *.csv file extension type file must be the file selected for data upload.	

IM	IMPORTANT			
Pri	ior to uploading data from your custom CSV file, please check this list to ensure the data is uploaded successfully.			
	The system will parse data using a comma as the field delimiter. Please ensure there are no commas within the values in the CSV file. For example, replace 1,000,250,CASE with 1000,250,CASE			
	Quotation marks should be excluded.			
	The system will only accept files with the <b>.csv</b> file extension type. Please make sure to save your file as a <b>.csv</b> file.			
	n, r, ran are all acceptable end of line (EOL) characters.			

No specific file encoding is enforced. Default and UTF-8 are both acceptable.

Remove all empty lines at the end of the CSV file that have only commas in them. These rows are usually only visible in a text editor (such as Notepad).

Ensure that you have included only permissible Business Operation values.

All DUNS, Business Operations, and NDCs must be entered in separate cells.

Every cell in columns A (Establishment DUNS), B (Business Operation), and C (NDC) must contain a value.

Do not include any special characters as separators in a cell.

Include leading zeroes for DUNS numbers to avoid validation errors. There should be a total of nine digits.

There should not be any blank rows.

Ensure to avoid duplicate entries or combinations of DUNS / NDCs / Business Operations.

#### SECTION 3.0 Common CSV File Upload Errors

There are five error types that may occur when uploading your CSV file:

- Parsing Error: This occurs if your CSV file was not able to process successfully. Please delete the old CSV file and upload a corrected CSV file.
- Hierarchy Error: This occurs if your CSV file was not processed. This occurs when a DUNS, Business Operation, and/or NDC is missing. Please note: Each DUNS must have at least one Business Operation, and each Business Operation must have at least one NDC. Please delete the old CSV file and upload a corrected CSV file.
- File Error: This occurs if the file name includes special characters (including blanks), or the file name is too long (more than 90 characters). Please delete the old CSV file and upload a new CSV file with an updated file name.
- Scanning Error: This occurs if your file is corrupt. Please delete the old CSV file and upload a new CSV file.
- Data Validation Issue: This occurs if the data provided does not match values in the drug registration and listing database. Please note: You may still submit your CARES Act Drug Amount Information Report with this issue.

Error Type	Common Issue	Resolution	Error Message on User Interface (UI)	
Parsing Error	Delimiter character is not a comma	The system will parse data using a comma as the delimiter. Please ensure there are no commas within the values in the CSV file. If punctuation is needed, please use a colon.	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.	
Parsing Error	Delimiter character is included in the data (e.g., "VIAL, GLASS").	The system will parse data using a comma as if it contains the delimiter. Please ensure there are no commas within the values in the CSV file. If punctuation is needed, please use a colon. For example: SYRINGE, GLASS should be updated to SYRINGE: GLASS	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.	
Parsing Error	The number of columns is not consistent with the CSV template	Update CSV file to adhere to the CSV template instructions.	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.	

If your CSV file upload results in an error, please review the suggested resolutions to the errors in the list below.

Parsing Error	Presence of nonprintable characters included in the CSV file	Adhere to the unicode UTF-8 encoding.	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.
Parsing Error	End of Line (EOL) Characters not accepted	Ensure that the encoding for the new line character is in UTF-8 format.	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.
Parsing Error	Headers do not match the CSV template	Copy and paste headers in the CSV template to avoid errors.	While processing, the system was not able to successfully parse the file. Please remove the CSV file, correct the data in the file, and upload the updated CSV file.
Parsing Error	Extra line-end commas	Remove the empty line provided in the error message.	While processing, the system was not able to successfully parse the file. Please remove the empty line xx for DUNS 123456789
Parsing Error	Empty comma lines	Remove the empty line provided in the error message.	While processing, the system was not able to successfully parse the file. Please remove the empty line xx for DUNS 123456789
Parsing Error	Misspelled or Duplicate Months	Correct the misspelled month or a month that has been entered twice for the line provided in the error message.	While processing, the system was not able to successfully parse the file. ABC month is misspelled on line xx for DUNS 123456789 OR ABC month is entered twice for DUNS 123456789
Parsing Error	Blank 21 CFR 314.81 annual total field	Enter an annual total value in the Intended to Fulfill 21 CFR 314.81 column for the given line provided in the error message.	While processing, the system was not able to successfully parse the file. Intended to Fulfill 21 CFR 314.81 annual total field is blank for DUNS 123456789

Parsing Error	Invalid 21 CFR 314.81 annual total value	Check that the annual total value for Intended to Fulfill 21 CFR 314.81 is either "Yes" or "No."	While processing, the system was not able to successfully parse the file. Intended to Fulfill 21 CFR 314.81 annual total field is inv for NDC 1234-1234-12 and DUNS 123456789	
Parsing Error	Mismatch between annual total and monthly 21 CFR 314.81 values	Ensure that the annual total value for Intended to Fulfill 21 CFR 314.81 matches any entered monthly values. Example: If the annual total value is "Yes," the monthly values can only be "Yes" or blank.	While processing, the system was not able to successfully parse the file. Please confirm that the entry in the Intended to Fulfill 21 CFR 314.81 annual total and monthly fields match (if entered) for NDC 1234-1234-12 and DUNS 123456789	
Parsing Error	Incorrect value for the Annual Total Line	Cross check the amounts for all months for the NDC number provided in the error message.	While processing, the system was not able to successfully parse the file. Please check the total amounts for NDC 1234-1234-12 and DUNS 123456789	
Hierarchy Error	DUNS, Business Operation, and/or NDC contains one or more missing values	Ensure that every DUNS, Business Operation, and NDC field contains a value.	<ul> <li>While processing, the system encountered one or more errors related to missing data.</li> <li>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</li> <li>Your file must contain at least one Establishment DUNS, at least one Business Operation for every Establishment DUNS entered, and at least one NDC for every Business Operation entered</li> </ul>	
Hierarchy Error	Delete cells in CSV file but not the entire row	Ensure that when you are removing data, to delete the entire row, not just the data in the cells	<ul> <li>While processing, the system encountered one or more errors related to missing data.</li> <li>Please remove the CSV file, correct the data in the file, and upload the updated CSV file.</li> <li>Your file must contain at least on Establishment DUNS, at least one Business Operation for every Establishment DUNS entered, and at least one NDC for every Business Operation entered</li> </ul>	

Validation Error	Unique DUNS/NDCs/Source NDCs are not found in the drug registration and listing database		Summary of data that does not match existing values in the drug registration and listing database. Unique DUNS not Validated in the FDA System: Unique NDCs not Validated in the FDA System Unique Source NDCs Not Validated in the FDA System Download the following file, Validation_Results.csv, for a list of data that does not match values in the drug registration and listing database. Validation_Results.csv Upon reviewing your data, you may wish to proceed with this data or make a correction. To make a correction, please remove the CSV file, correct the data in the file, and upload the updated CSV file.
File Error	Error in file name	Avoid special characters and blank spaces.	
File Error	Error in file length	Limit file name to 90 characters (excluding the extension).	

# Appendix

### Permissible Dosage Form Unit values

## Figure 2

AEROSOL	ENEMA	INJECTION: POWDER: LYOPHILIZED: FOR	PASTE: DENTIFRICE	STICK
		SUSPENSION		
Aerosol: foam	EXTRACT	INJECTION: POWDER:	PASTILLE	STRIP
		LYOPHILIZED: FOR		
		SUSPENSION: EXTENDED		
		RELEASE		
AEROSOL: METERED	FIBER: EXTENDED RELEASE	INJECTION: SOLUTION	PATCH	SUPPOSITORY
AEROSOL: POWDER	FILM	INJECTION: SOLUTION:	PATCH: EXTENDED	SUPPOSITORY: EXTENDED
		CONCENTRATE	RELEASE	RELEASE
AEROSOL: SPRAY	FILM: EXTENDED RELEASE	INJECTION: SUSPENSION	PATCH: EXTENDED	SUSPENSION
			RELEASE:	
			ELECTRICALLY	
			CONTROLLED	
ASEPTIC UTERINE INFUSION	FILM: SOLUBLE	INJECTION: SUSPENSION:	PELLET	SUSPENSION
		EXTENDED RELEASE		(INTRAMAMMARY)
BAR: CHEWABLE	FOR SOLUTION	INJECTION: SUSPENSION:	PELLET: IMPLANTABLE	SUSPENSION/ DROPS
		LIPOSOMAL		
BEAD	FOR SUSPENSION	INJECTION: SUSPENSION:	Pellets: Coated:	SUSPENSION: EXTENDED
		Sonicated	EXTENDED RELEASE	RELEASE
BEAD: IMPLANT: EXTENDED	FOR SUSPENSION:	INSERT	PILL	SUTURE
RELEASE	EXTENDED RELEASE			
BLOCK	GAS	INSERT: EXTENDED RELEASE	PINT	SWAB
BLOCK (TYPE C	GEL	INTRAUTERINE DEVICE	PLASTER	SYRUP
MEDICATED FEED)				
BOLUS	GEL: DENTIFRICE	IRRIGANT	POULTICE	TABLET
CAPSULE	GEL: METERED	JELLY	POWDER	TABLET WITH SENSOR
CAPSULE: COATED	GENERATOR	KILOGRAM: kg	POWDER:	TABLET: CHEWABLE
			DENTIFRICE	
CAPSULE: COATED PELLETS	GLOBULE	KIT	POWDER: FOR	TABLET: CHEWABLE:
			Solution	EXTENDED RELEASE
CAPSULE: COATED:	GRAFT	LINER: DENTAL	POWDER: FOR	TABLET: COATED
EXTENDED RELEASE			SUSPENSION	

CAPSULE: DELAYED RELEASE	GRAM: g	LINIMENT	POWDER: METERED	TABLET: COATED PARTICLES
CAPSULE: DELAYED RELEASE PELLETS	GRANULE	LIPSTICK	POWDER: TYPE A MEDICATED ARTICLE	TABLET: DELAYED RELEASE
CAPSULE: EXTENDED RELEASE	GRANULE (TYPE A MEDICATED ARTICLE)	LIQUID	POWDER: TYPE B MEDICATED FEED	TABLET: DELAYED RELEASE PARTICLES
CAPSULE: FILM COATED: EXTENDED RELEASE	GRANULE (TYPE A MEDICATED ARTICLE: TYPE B MEDICATED FEED)	LIQUID (SOLUTION) - INTRAVENOUS: INTRAMUSCULAR: SUBCUTANEOUS	QUART	TABLET: EFFERVESCENT
CAPSULE: GELATIN COATED	GRANULE (TYPE A MEDICATED ARTICLE: TYPE C MEDICATED FEED)	LIQUID (TYPE A MEDICATED ARTICLE)	RING	TABLET: EXTENDED RELEASE
CAPSULE: LIQUID FILLED	GRANULE (TYPE B MEDICATED FEED)	LIQUID CONCENTRATE	RINSE	TABLET: FILM COATED
CEMENT	GRANULE: DELAYED RELEASE	LIQUID: EXTENDED RELEASE	SALVE	TABLET: FILM COATED: EXTENDED RELEASE
CIGARETTE	GRANULE: EFFERVESCENT	LITER: L	Shampoo	TABLET: FOR SOLUTION
CLOTH	GRANULE: FOR SOLUTION	LOTION	Shampoo: Suspension	TABLET: FOR SUSPENSION
CONCENTRATE	GRANULE: FOR SUSPENSION	LOTION/SHAMPOO	SOAP	TABLET: MULTILAYER
CONCENTRATE SOLUTION	GRANULE: FOR SUSPENSION: EXTENDED RELEASE	LOTION: AUGMENTED	SOLUBLE POWDER	TABLET: MULTILAYER: EXTENDED RELEASE
CONE	GUM	LOZENGE	SOLUBLE POWDER DRINKING WATER	TABLET: ORALLY DISINTEGRATING
CORE: EXTENDED RELEASE	GUM: CHEWING	MEDICATED FEED	SOLUTION	TABLET: ORALLY DISINTEGRATING: DELAYED RELEASE
CREAM	GUM: RESIN	MILLIGRAM: mg	solution/ drops	TABLET: SOLUBLE
CREAM: AUGMENTED	IMPLANT	MILLILITER: mL	Solution: concentrate	TABLET: SUGAR COATED
CRYSTAL	INHALANT	MOUTHWASH	Solution: for Slush	TAMPON
CULTURE	INJECTABLE: LIPOSOMAL	NOT APPLICABLE	SOLUTION: GEL FORMING / DROPS	ТАРЕ
CURIE: Ci	INJECTION	NUFLOR 2.3% SOLUTION CONCENTRATE 2.2 LITER	SOLUTION: GEL FORMING: EXTENDED RELEASE	TINCTURE

DIAPHRAGM	INJECTION: EMULSION	NUFLOR INJECTION SOLUTION 100ML: 250ML: 500ML	Sponge	TROCHE
DISC	INJECTION: LIPID COMPLEX	OIL	SPRAY	TYPE A MEDICATED ARTICLE
DOUCHE	INJECTION: POWDER: FOR SOLUTION	OINTMENT	SPRAY: METERED	TYPE A MEDICATED ARTICLE & TYPE B MEDICATED FEED (POWDER)
DRESSING	INJECTION: POWDER: FOR SUSPENSION	OINTMENT: AUGMENTED	SPRAY: SUSPENSION	UNASSIGNED
DRUG DELIVERY SYSTEM	INJECTION: POWDER: FOR SUSPENSION: EXTENDED RELEASE	ORAL SOLUTION	SQUARE CENTIMETER: cm2	WAFER
ELIXIR	INJECTION: POWDER: LYOPHILIZED: FOR LIPOSOMAL SUSPENSION	PACKING	STERILE POWDER	WATER SOLUBLE POWDER
Emulsion	INJECTION: POWDER: LYOPHILIZED: FOR SOLUTION	PASTE	STERILE POWDER FOR SUSPENSION	

# Appendix (continued)

### How to preserve leading zeroes in Excel.

### Figure 3

-igure 3	
1. Select the column you wish to enter leading zeroes into.	A1 F   Establishment DUNS Business Operation NDC   2   3   4   5   6   7   8   9   10   11   12   13
2. Right-click, and select <b>Format Cells.</b>	A1 Calibri $11 \rightarrow A^{A} \times 5 \rightarrow 69$ Establishr B $I \equiv 2 \rightarrow A \rightarrow 11 \rightarrow 10$ B $I \equiv 2 \rightarrow 4 \rightarrow 11 \rightarrow 10$ B $I \equiv 2 \rightarrow 4 \rightarrow 11 \rightarrow 10$ Copy Copy F Copy Paste Options: 7 8 9 9 9 9 9 9 9 9 9 9 9 9 9

